

WHAT IS CLAIMED IS:

1. A catheter to be percutaneously inserted into a living body lumen, said catheter comprising:

a sheath portion having a lumen extending therein,
5 an insertion member slidably disposed in said lumen of said sheath portion and having a distal end portion capable of protruding from a distal end portion of said sheath portion,
an injection needle disposed at said distal end portion of said insertion member for injecting a therapeutic
10 composition into a target tissue in a living body, and
an electrode disposed at a distal end portion of said catheter for measuring a cardiac action potential.

2. The catheter as set forth in claim 1, wherein said target tissue is a cardiac tissue.

15 3. The catheter as set forth in claim 1, wherein said therapeutic composition contains a nucleic acid, a protein, or cells.

4. The catheter as set forth in claim 1, wherein said distal end portion of said sheath portion is provided with
20 a through-hole communicated with said lumen.

5. The catheter as set forth in claim 4, wherein said through-hole is spaced by not less than 1 mm from an end face of said distal end portion of said sheath portion along the longitudinal direction of said sheath portion.

25 6. The catheter as set forth in claim 1, wherein a plurality of said electrodes are provided.

7. The catheter as set forth in claim 1, wherein said electrode is disposed at each of said distal end portion of said insertion member and/or said distal end portion of said
30 sheath portion.

8. The catheter as set forth in claim 7, wherein said electrode disposed at said distal end portion of said insertion

member is provided at a bevel of said injection needle.

9. The catheter as set forth in claim 7, wherein said electrode disposed at said distal end portion of said insertion member is located at an outer circumferential surface of said distal end portion of said insertion member.

10. The catheter as set forth in claim 9, wherein a plurality of said electrodes are disposed at said distal end portion of said insertion member in the state of being spaced from each other along the longitudinal direction of said insertion member.

11. The catheter as set forth in claim 7, wherein said electrode disposed at said distal end portion of said insertion member is spaced by not less than 1 mm from the distal end of said injection needle along the longitudinal direction of said insertion member.

12. A catheter system comprising:
a catheter to be percutaneously inserted into a living body lumen, said catheter comprising a sheath portion having a lumen extending therein, an insertion member slidably disposed in said lumen of said sheath portion and having a distal end portion capable of protruding from a distal end portion of said sheath portion, and an injection needle disposed at said distal end portion of said insertion member for injecting a therapeutic composition into a target tissue in a living body;

a first electrode disposed at a distal end portion of said catheter for measuring a cardiac action potential;

a second electrode for measuring said cardiac action potential; and

a puncture detection unit to which a conductor extending from said first electrode and a conductor extending from said second electrode are connected and which detects the puncture

by said injection needle based on said cardiac action potential measured by said first electrode and said second electrode.

13. The catheter system as set forth in claim 12, wherein said second electrode is disposed at a distal end portion of said catheter, and is located on the side of the proximal end of said catheter relative to said first electrode.

14. The catheter system as set forth in claim 12, wherein said second electrode is provided as a separate body independent from said catheter.

15. A method of injecting a therapeutic composition by use of a catheter to be percutaneously inserted into a living body lumen, said catheter comprising a sheath portion having a lumen extending therein, an insertion member slidably disposed in said lumen of said sheath portion and having a distal end portion capable of protruding from a distal end portion of said sheath portion, an injection needle disposed at said distal end portion of said insertion member for injecting said therapeutic composition into a target tissue, and an electrode disposed at a distal end portion of said catheter for measuring a cardiac action potential, said method comprising the steps of:

(a) inserting said catheter into a living body and advancing said catheter to the vicinity of said target tissue; and

(b) puncturing said target tissue by said injection needle and injecting said therapeutic composition into said target tissue through said injection needle, based on said cardiac action potential measured by said electrode.

16. The method as set forth in claim 15, wherein said electrode is disposed at said distal end portion of said insertion member, and

said step (b) comprises the steps of:

moving said insertion member in the distal direction relative to said sheath portion to thereby protruding said injection needle from said distal end portion of said sheath portion, thereby puncturing said target tissue by said injection needle, while measuring said cardiac action potential by said electrode; and

injecting said therapeutic composition into said target tissue through said injection needle, after a change is detected in said cardiac action potential measured by said electrode.

17. The method as set forth in claim 15, wherein said electrode is disposed at said distal end portion of said sheath portion, and

said step (b) comprises the steps of:
bringing said distal end portion of said sheath portion into contact with said target tissue while measuring said cardiac action potential by said electrode;

detecting a change in the cardiac action potential measured by the electrode;

moving said insertion member in the distal direction relative to said sheath portion to thereby protrude said injection needle from said distal end portion of said sheath portion, thereby puncturing said target tissue by said injection needle, while further measuring said cardiac action potential by said electrode, after the change is detected in said cardiac action potential measured by said electrode; and

injecting said therapeutic composition into said target tissue through said injection needle, after it is confirmed that no change is generated in said cardiac action potential measured by said electrode while moving the insertion member in the distal direction.